# In the United States Court of Federal Claims

# **OFFICE OF SPECIAL MASTERS**

No. 23-1325V UNPUBLISHED

SHELLY WIGLER, on behalf of her minor child, A.W.,

Chief Special Master Corcoran

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Filed: April 11, 2024

*Michelle Greene*, The Lanier Law Firm, PLLC, New York, NY, for Petitioner. *Julia M. Collison*, U.S. Department of Justice, Washington, DC, for Respondent.

#### **DECISION**<sup>1</sup>

On August 16, 2023, Shelly Wigler filed a petition for compensation on behalf of her minor child, A.W., under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa—10 through 34 (the "Vaccine Act"). Petitioner alleges that A.W. suffered various injuries from human papillomavirus ("HPV") vaccinations she received on October 4, 2019, and May 6, 2021. ECF No. 1 at 2.

Because the petition was untimely filed, and Petitioner has failed to establish a basis for equitable tolling, Respondent's motion to dismiss is **GRANTED** and this case is **DISMISSED**.

# **Relevant Factual Background**

On October 4, 2019, at the age of thirteen, A.W. went with her mother, Petitioner, to a well visit where A.W. received the first dose of the HPV vaccine. Exhibit 4 at 65. At this appointment, the records state that the physician's assistant provided A.W. and her mother with a Vaccine Information Statement (VIS) and counseled them on the "[n]eed for vaccine, risks, benefits, [and] potential side effects." *Id.* 

<sup>&</sup>lt;sup>1</sup> Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <a href="https://www.govinfo.gov/app/collection/uscourts/national/cofc">https://www.govinfo.gov/app/collection/uscourts/national/cofc</a>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

A "couple of months" after the first vaccination, A.W. started having abdominal pain and would experience dizziness and pre-syncope when moving positions. ECF No. 1 ¶ 5; exhibit 2 at 92 (abdominal pain began one to two months before April 30, 2020 appointment). A.W. was diagnosed with postural orthostatic tachycardia syndrome (POTS) in June 2020.<sup>2</sup> *Id.* ¶ 6.

On May 6, 2021, at the age of fourteen, A.W. went with her mother to receive the second dose of the HPV vaccine. Exhibit 4 at 49. At this appointment, the records state that a nurse provided A.W. and her mother with a VIS and counseled them on the "[n]eed for vaccine, risks, benefits, [and] potential side effects." *Id.* 

Petitioner alleged the preceding medical history in the petition and repeated the history in her response to the motion to dismiss. Facially, Petitioner's claim herein was filed almost four years after A.W.'s first HPV dose, which was administered in October 2019, and around three and a half years from the time she began manifesting symptoms in March 2020. But Petitioner maintains her delay is excusable. In the response to the motion to dismiss, Petitioner stated at the time this vaccination occurred, no one discussed the possible adverse side effects of the HPV vaccine, no VIS was provided, and no information was relayed about the Vaccine Program. ECF No. 13 at 11. Although Petitioner asserts that she "testified" about these statements, none of these statements were included in Petitioner's affidavit. Exhibit 1. Petitioner stated that she did not learn about the Vaccine Program until July 2023, but she filed a vaccine claim soon after. ECF No. 13 at 11. Again, Petitioner did not attest to this statement in her affidavit and only stated it in the response to the motion to dismiss. Exhibit 1.

# **Relevant Procedural History**

On November 7, 2023, Respondent filed a motion to dismiss arguing that the claim had been filed outside the Vaccine Act's 36-month statute of limitations, Sec. 16(a)(2). ECF No. 11. Respondent maintained that Petitioner had not diligently pursued her rights before filing a vaccine claim in 2023. Respondent also disputed the veracity of contentions about the manufacturer's conduct, and whether it could in any event constitute an extraordinary circumstance that would serve as a basis for tolling the statute of limitations.

On December 19, 2023, Petitioner filed a response. ECF No. 13. Petitioner did not dispute the onset of symptoms in March 2020, or that her petition was filed in August 2023 (and not sooner than March 2023, the statute of limitations deadline), but instead argued that the limitations period should be equitably tolled. Petitioner asserted that she

<sup>&</sup>lt;sup>2</sup> The PAR Questionnaire appears to also allege celiac disease as a vaccine injury, but neither the petition nor Petitioner's affidavit make this allegation.

had diligently pursued A.W.'s rights once she realized the connection between A.W.'s injuries and the HPV vaccine and became aware of the Vaccine Program. Petitioner also made allegations not relevant to a Vaccine Act claim, about the perfidious conduct of the vaccine manufacturer in fraudulently concealing the HPV vaccine's harmful character from the public. ECF No. 13 at 15. Relatedly, Petitioner argued that the failure of a healthcare professional to provide her with a Vaccine Information Statement at the time of vaccination on behalf of A.W. can be attributed to the Department of Health and Human Services' failure to systematically ensure that VIS are provided and explained to all vaccine recipients. *Id.* at 3.

Respondent did not file a reply to Petitioner's response.

# Legal Standards

The Vaccine Act's statute of limitations is thirty-six months. Sec. 16(a)(2). The statute begins to run from the manifestation of the first objectively cognizable symptom, whether or not that symptom is sufficient for diagnosis (or even recognized by a claimant as significant). *Id.*; *Carson v. Sec'y of Health & Hum. Servs.*, 727 F.3d 1365, 1369 (Fed. Cir. 2013).

The Federal Circuit has held that the doctrine of equitable tolling can apply to Vaccine Act's statute of limitations. See Cloer v. Sec'y of Health & Hum. Servs., 654 F.3d 1322, 1340-41 (Fed. Cir. 2011). However, in keeping with applicable U.S. Supreme Court precedent, equitable tolling of a limitations period is to be permitted "sparingly." Irwin v. Dep't of Veterans Affairs, 498 U.S. 89, 96, (1990). The appropriateness of equitable tolling is ultimately to be determined on a case-by-case basis, without rigid application of any relevant overarching guidelines. Holland v. Florida, 560 U.S. 631, 649–50 (2010); accord Arctic Slope Native Ass'n v. Sebelius, 699 F.3d 1289, 1295 (Fed. Cir. 2012).

Petitioners must prove two elements to establish equitable tolling: (1) that petitioner diligently pursued her rights, and (2) an extraordinary circumstance prevented her from timely filing the claim. *K.G. v. Sec'y of Health & Hum. Servs.*, 951 F.3d 1374, 1379 (Fed. Cir. 2020) (citing *Menominee Indian Tribe v. United States*, 577 U.S. 250, 255 (2016)). When first articulating this limited exception to equitable tolling, the Federal Circuit primarily enumerated fraud and duress—but not, for example, *lack of awareness* on a petitioner's part that she might have an actionable claim. *Cloer*, 654 F.3d at 1344–45 (noting that tolling of the Vaccine Act's statute of limitations period is not triggered "due to unawareness of a causal link between an injury and administration of a vaccine").

In *K.G.*, 951 F.3d at 1380–82 (Fed. Cir. 2020), the Circuit more explicitly endorsed the proposition that an individual's demonstrated mental incapacity could be a basis for equitable tolling in the Program. For a mentally incapacitated individual, the Circuit

instructed that the details of the individual's relationship with her legal guardian would affect whether there was reasonable diligence or extraordinary circumstances. *K.G.*, 951 F.3d at 1382 (Fed. Cir. 2020). More recently, the Circuit concluded that a parent acting as a legal guardian did not have extraordinary circumstances preventing the filing of a petition where the parent: (1) routinely made medical decisions on behalf of the legally incapacitated individual during the relevant time period, (2) had no documented strained relationship with the individual, and (3) had no conflicts of interest dissuading the parent from filing a petition. *W.J. v. Sec'y of Health & Hum. Servs.*, 93 F.4th 1228, 1241 (Fed. Cir. 2024).

#### **Analysis**

The untimeliness of this filing is acknowledged by Petitioner, so the only question to be resolved is whether equitable tolling should save the claim. But Petitioner has failed to establish both elements of equitable tolling – diligent pursuit and extraordinary circumstances.

## A) Diligent pursuit

Petitioner stated that she diligently began to pursue A.W.'s claim after she learned about the Vaccine Program in July 2023.<sup>3</sup> Petitioner argues that her diligent pursuit of A.W.'s vaccine claim was impeded by A.W.'s minor status since the vaccine was administered.

These arguments are wholly unpersuasive. It is beyond question that claims asserted in the Vaccine Program are not subject to a "discovery rule," accruing only when a claimant *learns* he or she might possess a cause of action. Rather, the statute of limitations period is triggered by the onset of Petitioner's symptoms – whether or not onset was understood to be the start of the claimed injurious illness or condition. *Cloer v. Sec'y of Health & Hum. Servs.*, 654 F.3d 1322, 1340 (Fed. Cir. 2011) (en banc). And the failure to be advised of the Vaccine Program or the Act does not support equitable tolling of the statute of limitations period for an otherwise-untimely filed petition. *Speights v. Sec'y of Health & Hum. Servs.*, No. 03-2619V, 2013 WL 5944084, at \*13 (Fed. Cl. Spec. Mstr. Oct. 17, 2013). Thus, a petitioner cannot generally shield an untimely claim from dismissal by asserting, even in good faith, that she literally was unaware of her Vaccine Act "rights."

Petitioner attempts to leverage A.W.'s minor status at the time of vaccination into an exception to the above. The Federal Circuit has conclusively stated that Vaccine Act

<sup>&</sup>lt;sup>3</sup> As noted above, Petitioner has not attested to when she learned about the Vaccine Program or began to diligently pursue A.W.'s vaccine claim. Exhibit 1 (affidavit). Petitioner has only made these statements in the response to the motion to dismiss. ECF No. 13.

does <u>not</u> contain a provision for minority tolling and that Congress did <u>not</u> intend to allow minority tolling. *W.J.*, 93 F.4th at 1241. The only savings clause in the Act is for revisions to the Vaccine Injury Table, which allow an otherwise untimely claim for newly added vaccines to be filed. Sec. 16(b). And there is no argument here that a Table claim specifically involving the HPV vaccine was added that would cover Petitioner's delayed filing.<sup>4</sup>

# B) Extraordinary Circumstances

Petitioner's arguments about the purported fraudulent conduct of the vaccine's manufacturer, in hiding proof of the vaccine's dangers, deserve even less consideration. ECF No. 13 at 15. As a threshold matter, these contentions are speculative and not evidentiarily-supported. And regardless of their actual truth, the fact remains that the Government *has approved* the HPV vaccine for administration to minors, rendering it "covered" under the Act.<sup>5</sup> The only issue to be resolved in a Program case is whether (assuming, as here, the claim is not a Table claim) the claim meets the standards for causation – and those standards have nothing to do with a manufacturer's alleged misconduct in preparation or promotion of the underlying vaccine.

These allegations also are not a basis for tolling under the circumstances. Petitioner simply has not shown that contentions of corporate misconduct not specific to, or directed at, her personally could rise to the level of the kind of "fraud" that might excuse failing to file a Program claim in a timely manner. Nor has she persuasively established that the vaccine administrator's "failure to warn," or provide a VIS in 2019 or 2021, is an extraordinary circumstance. Even assuming the factual accuracy of that allegation, it remains the case (as the Circuit recognized in *Cloer*) that vaccine claims accrue upon onset – and that the failure to be advised of the Vaccine Program does not support equitable tolling. *Cloer*, 654 F.3d at 1340; see also Speights, 2013 WL 5944084, at \*13. And arguments about governmental agency knowledge of a failure to warn reflect

<sup>&</sup>lt;sup>4</sup> In fact, the HPV vaccine was added to the Table in 2007 – almost *thirteen* years before onset is alleged herein to have occurred. 42 C.F.R. § 100.3 (Vaccine Injury Table); National Vaccine Injury Compensation Program: Addition of Meningococcal and Human Papillomavirus (HPV) Vaccines to the Vaccine Injury Table, 72 Fed. Reg. 19937 (Apr. 20, 2007). The Act's lookback provisions have no relevance at all to the timeliness of this claim.

<sup>&</sup>lt;sup>5</sup> The HPV vaccine was first added to the Table in 2007. 42 C.F.R. § 100.3 (Vaccine Injury Table); National Vaccine Injury Compensation Program: Addition of Meningococcal and Human Papillomavirus (HPV) Vaccines to the Vaccine Injury Table, 72 Fed. Reg. 19937 (Apr. 20, 2007).

<sup>&</sup>lt;sup>6</sup> Petitioner has only stated in the response to the motion to dismiss, not attested in an affidavit, that she did not receive vaccine counseling, a VIS, or any information about the Vaccine Program during the HPV vaccination appointments. ECF No. 13 at 11. The medical records for both vaccination appointment state that Petitioner and A.W. were provided with VIS and vaccine counseling regarding the benefits, risks, and potential side effects of the HPV vaccine. Exhibit 4 at 49, 65.

overheated, almost-conspiratorial allegations that do not come close to excusing the claim's untimely nature.

Finally, Petitioner also asserts that the safety of the HPV vaccine is "in dispute [and] the Court should not simply accept the assertions of the Respondent over those of the Petitioner without further proceedings including expert testimony on the subject." ECF No. 13 at 2. But this argument willfully ignores the extent to which I have personally ruled in numerous prior cases that medical science does not preponderantly support the contention that the HPV vaccine can cause POTS. See, e.g., J.S. v. Sec'y of Health & Hum. Servs., No. 16-1083V, 2022 WL 20213038, at \*20 (Fed. Cl. Spec. Mstr. July 15, 2022), mot. for review denied, 164 Fed. Cl. 314 (2023), appeal docketed, No. 23-1644 (Fed. Cir. Mar. 22, 2023); Hughes v. Sec'y of Health & Hum. Servs., No. 16-930V, 2021 WL 839092, at \*31 (Fed. Cl. Spec. Mstr. Jan. 4, 2021), mot. for review denied, 154 Fed. Cl. 640 (2021); E.S. v. Sec'y of Health & Hum. Servs., No. 17-480V, 2020 WL 9076620, at \*40, 43 (Fed. Cl. Spec. Mstr. Nov. 13, 2020), mot. for review denied, 154 Fed. Cl. 149 (2021); McKown v. Sec'y of Health & Hum. Servs., No. 15-1451V, 2019 WL 4072113, at \*44-45 (Fed. Cl. Spec. Mstr. July 15, 2019). The Act does not require that the same theory rejected so many times before must be relitigated by the Program ad infinitum (especially in the absence of new compelling evidence). Rather, special masters are expressly empowered to rely on their expertise, earned in adjudicating Program cases, in subsequent similar matters. To suggest that they should ignore what they have learned in that process reveals a complete miscomprehension of the Program's underlying goals and purposes.

## Conclusion

Thus, Petitioner has failed to establish equitable tolling. This case is dismissed for being untimely filed. The Clerk of Court shall enter judgment accordingly.<sup>7</sup>

IT IS SO ORDERED.

s/Brian H. Corcoran Brian H. Corcoran Chief Special Master

<sup>&</sup>lt;sup>7</sup> If Petitioner wishes to bring a civil action, she must file a notice of election rejecting the judgment pursuant to § 21(a) "not later than 90 days after the date of the court's final judgment."